

DOCKET NO.: PUJ-0279
Application No.: 09/634,399
Office Action Dated: November 6, 2003

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. **(Previously Presented)** A composition in the form of a single-phase gel comprising minoxidil, a non-carbomeric organic thickening agent, and a pharmaceutically acceptable solvent, wherein said minoxidil is present at a concentration which is less than its solubility limit in said composition, and said non-carbomeric thickening agent is other than hydroxypropyl cellulose.
2. **(Cancelled)**
3. **(Original)** A composition of claim 1 which comprises from greater than about 0.01% to about 8% minoxidil.
4. **(Original)** A composition of claim 3 which comprises from greater than about 3% to about 8% minoxidil.
5. **(Original)** A composition of claim 4 which comprises from about 5% to about 6% minoxidil.
6. **(Original)** A composition of claim 5 which comprises about 5% minoxidil.
7. **(Original)** A composition of claim 1, wherein said pharmaceutically acceptable solvent is selected from the group consisting of alcohols and polyols.
8. **(Original)** A composition of claim 7, wherein said solvent comprises an alcohol.
9. **(Original)** A composition of claim 8, wherein said alcohol is selected from the group consisting of ethanol, propanol, and butanol.

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10. **(Original)** A composition of claim 9, wherein said alcohol is selected from the group consisting of ethanol and isopropanol.
11. **(Original)** A composition of claim 7, wherein said solvent comprises a polyol.
12. **(Original)** A composition of claim 11, wherein said polyol comprises a glycol.
13. **(Original)** A composition of claim 12, wherein said glycol is selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.
14. **(Original)** A composition of claim 13, wherein said glycol is propylene glycol.
15. **(Original)** A composition of claim 7, wherein said solvent comprises a mixture of an alcohol and a glycol.
16. **(Original)** A composition of claim 15, wherein said solvent comprises a mixture of ethanol and propylene glycol.
17. **(Original)** A composition of claim 1, further comprising a neutralizing agent.
18. **(Original)** A composition of claim 17, wherein said neutralizing agent is selected from the group consisting of ammonium hydroxide, arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-sec-butanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine, tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, aminomethyl propanol, sodium hydroxide, and potassium hydroxide.

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19. **(Original)** A composition of claim 18, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine.
20. **(Original)** A composition of claim 19, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.
21. **(Original)** A composition of claim 1, wherein said solvent is present in said composition in an amount of at least about 20%.
22. **(Previously Presented)** A composition of claim 21 which comprises from about 20% to about 99% of said solvent.
23. **(Previously Presented)** A composition of claim 1, further comprising pharmaceutically acceptable additives and ingredients selected from the group consisting of hair conditioners, panthenol, calcium pantothenate, colorants, fragrances, fragrance modifiers, vitamin E, penetration modifiers, surfactants, cosmetic agents, fatty acids and fatty acid esters, herbal extracts, henna, oils, emulsifiers, wetting agents, sunscreens, and anti-irritants.
24. **(Cancelled)**
25. **(Previously Presented)** A composition of claim 1, wherein said non-carbomeric thickening agent comprises an organic thickening agent which is a polymer.
26. **(Original)** A composition of claim 25, wherein said polymer is selected from the group consisting of starches, gums, pectin, casein, gelatin, phycocolloids, and synthetic polymers.

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27. **(Withdrawn)** A composition of claim 26, wherein said polymer is selected from the group consisting of alginates and salts and derivatives thereof, acacia, carrageenan, guar gum, karaya gum, locust bean gum, tragacanth, xanthan gum, carboxymethylcellulose and salts thereof, ethylcellulose, hydroxyethylcellulose, methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, cellulose, hyaluronic acid and salts thereof, and polydextrose.

28. **(Previously Presented)** A composition of claim 27, wherein said polymer is selected from the group consisting of crosslinked copolymers of acrylic acid, dimethicone copolyols, acrylic/acrylate copolymers, polyacrylamide, ethylene/sodium acrylate copolymer, acrylamide/sodium acrylate copolymer, sodium acrylate/vinyl alcohol copolymer, sodium polymethacrylate, sodium polystyrene sulfonate, povidone, polyquaternium compounds, polyvinyl alcohol, polyethylene oxide, and poloxamers.

29. **(Original)** A composition of claim 28, wherein said polymer comprises a crosslinked copolymer of acrylic acid.

30. **(Original)** A composition of claim 29, wherein said crosslinked copolymer of acrylic acid comprises an acrylate/C₁₀₋₃₀ alkyl acrylate crosspolymer.

31. **(Cancelled)**

32. **(Cancelled)**

33. **(Currently Amended)** A composition of claim 2 1, wherein said thickening agent comprises a crosslinked copolymer of acrylic acid.

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34. **(Original)** A composition of claim 33, wherein said crosslinked copolymer of acrylic acid comprises an acrylate/C₁₀₋₃₀ alkyl acrylate crosspolymer.

35. **(Original)** A composition of claim 33 wherein said solvent is present in said composition in an amount of at least about 20%.

36. **(Previously Presented)** A high solvent/low water composition in the form of a single-phase gel comprising greater than 3% minoxidil, greater than about 50% of a pharmaceutically acceptable solvent selected from the group consisting of alcohols and polyols, up to about 25% water, and a solvent-tolerant carbomer, wherein said minoxidil is present at a concentration which is less than its solubility limit in said composition.

37. **(Cancelled)**

38. **(Original)** A composition of claim 36 which comprises from greater than 3% to about 8% minoxidil.

39. **(Original)** A composition of claim 38 which comprises from about 4% to about 7% minoxidil.

40. **(Original)** A composition of claim 39 which comprises from about 5% to about 6% minoxidil.

41. **(Original)** A composition of claim 40 which comprises about 5% minoxidil.

42. **(Cancelled)**

43. **(Previously Presented)** A composition of claim 36, wherein said solvent comprises an alcohol.

44. **(Original)** A composition of claim 43, wherein said alcohol is selected from the group consisting of ethanol, propanol, and butanol.
45. **(Original)** A composition of claim 44, wherein said alcohol is selected from the group consisting of ethanol and isopropanol.
46. **(Previously Presented)** A composition of claim 36 wherein said solvent comprises a polyol.
47. **(Original)** A composition of claim 46, wherein said polyol comprises a glycol.
48. **(Original)** A composition of claim 47, wherein said glycol is selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.
49. **(Original)** A composition of claim 48, wherein said glycol is propylene glycol.
50. **(Previously Presented)** A composition of claim 36, wherein said solvent comprises a mixture of an alcohol and a glycol.
51. **(Original)** A composition of claim 50, wherein said solvent comprises a mixture of ethanol and propylene glycol.
52. **(Previously Presented)** A composition of claim 36, further comprising a neutralizing agent.
53. **(Original)** A composition of claim 52, wherein said neutralizing agent is selected from the group consisting of arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-sec-

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butanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine, tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, and aminomethyl propanol.

54. **(Original)** A composition of claim 53, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine.

55. **(Original)** A composition of claim 54, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.

56. **(Cancelled)**

57. **(Previously Presented)** A composition of claim 36 which comprises from about 20% to about 99% of said solvent.

58. **(Previously Presented)** A composition of claim 57 wherein the ratio of said solvent to minoxidil is about 10:1.

59. **(Previously Presented)** A composition of claim 58 wherein the ratio of said solvent to minoxidil is about 12:1.

60. **(Previously Presented)** A composition of claim 59 wherein the ratio of said solvent to minoxidil is about 15:1.

61. **(Previously Presented)** A composition of claim 36, further comprising pharmaceutically acceptable additives and ingredients selected from the group consisting of hair conditioners, panthenol, calcium pantothenate, colorants, fragrances, fragrance

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modifiers, vitamin E, penetration modifiers, surfactants, cosmetic agents, fatty acids and fatty acid esters, herbal extracts, henna, oils, emulsifiers, wetting agents, sunscreens, and anti-irritants.

62. **(Previously Presented)** A composition in the form of a single-phase gel comprising:
from greater than about 3% to about 8% of minoxidil;
from about 30% to about 80% of a polyol;
from about 10% to about 50% of an alcohol;
from about 0.01% to about 50% of a non-carbomeric polymer;
from about 0% to about 3% of a neutralizing agent; and
water (qs); wherein said minoxidil is present at a concentration which is less than its solubility limit in said composition, and said non-carbomeric polymer is other than hydroxypropyl cellulose.

63. **Cancelled**

64. **(Original)** A composition of claim 62, wherein said polyol comprises a glycol.

65. **(Original)** A composition of claim 64, wherein said glycol is selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.

66. **(Original)** A composition of claim 65, wherein said glycol is propylene glycol.

67. **(Original)** A composition of claim 62, wherein said alcohol is selected from the group consisting of ethanol, propanol, and butanol.

68. **(Original)** A composition of claim 67, wherein said alcohol is selected from the group consisting of ethanol and isopropanol.
69. **(Original)** A composition of claim 62, wherein said non-carbomeric thickening agent comprises a crosslinked copolymer of acrylic acid.
70. **(Original)** A composition of claim 69 wherein said crosslinked copolymer of acrylic acid comprises an acrylate/C₁₀₋₃₀ alkyl acrylate crosspolymer.
71. **(Original)** A composition of claim 62, wherein said neutralizing agent is selected from the group consisting of arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-sec-butanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine, tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, and aminomethyl propanol.
72. **(Original)** A composition of claim 71, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine, and mixtures thereof.
73. **(Original)** A composition of claim 72, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.
74. **(Original)** A composition of claim 62, comprising:
from about 4% to about 7% of minoxidil;
from about 40% to about 70% of a polyol;
from about 20% to about 30% of an alcohol;
from about 0.05% to about 3% of a non-carbomeric polymer; and
from about 0.03% to about 1% of a neutralizing agent.

75. **(Original)** A composition of claim 74, comprising:
from about 5% to about 6% of minoxidil;
from about 50% to about 60% of a polyol; and
from about 25% to about 30% of an alcohol.

76. **(Original)** A composition of claim 74 comprising:
about 5% of minoxidil;
about 53% of a polyol;
about 26% of an alcohol;
from about 0.25% to about 1% of a non-carbomeric polymer; and
from about 0.15% to about 0.6% of a neutralizing agent.

77. **(Withdrawn)** A composition of claim 62, wherein said non-carbomeric polymer is selected from the group consisting of alginates and salts, acacia, carrageenan, guar gum, karaya gum, locust bean gum, tragacanth, xanthan gum, carboxymethylcellulose and salts thereof, ethylcellulose, hydroxyethylcellulose, methylcellulose, hydroxypropyl methylcellulose, cellulose, hyaluronic acid and salts thereof, and polydextrose.

78. **(Previously Presented)** A composition of claim 62, wherein said non-carbomeric polymer is selected from the group consisting of crosslinked copolymers of acrylic acid, dimethicone copolyols, acrylic/acrylate copolymers, polyacrylamide, ethylene/sodium acrylate copolymer, acrylamide/sodium acrylate copolymer, sodium acrylate/vinyl alcohol copolymer, sodium polymethacrylate, sodium polystyrene sulfonate, povidone, polyquaternium compounds, polyvinyl alcohol, polyethylene oxide, and poloxamers.

79 - 110 **(Cancelled)**

111. **(Previously Presented)** A method comprising topically administering a composition according to claim 1 to a region of hair loss on a patient.

112. **(Original)** A method according to claim 111, wherein said hair loss comprises androgenetic alopecia, frontal hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen hair loss, diffuse alopecia, and telogen effluvium.

113. **(Previously Presented)** A method comprising topically administering a composition according to claim 36 to a region of hair loss on a patient.

114. **(Original)** A method according to claim 113, wherein said hair loss comprises androgenetic alopecia, frontal hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen hair loss, diffuse alopecia, and telogen effluvium.

115. **(Previously Presented)** A method comprising topically administering a composition according to claim 62 to a region of hair loss on a patient.

116. **(Original)** A method according to claim 115, wherein said hair loss comprises androgenetic alopecia, frontal hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen hair loss, diffuse alopecia, and telogen effluvium.

117 - 119. **(Cancelled)**

120. **(Newly added)** A composition of claim 34 comprising:
 from about 4% to about 7% of minoxidil;

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from about 40% to about 70% of a polyol;
from about 20% to about 30% of an alcohol;
from about 0.05% to about 3% of an acrylate/C₁₀₋₃₀ alkyl acrylate crosspolymer.

121. **(Newly added)** A composition of claim 120 comprising:

from about 5% to about 6% of minoxidil;
from about 50% to about 60% of a polyol; and
from about 25% to about 30% of an alcohol.

122. **(Newly added)** A composition of claim 121 comprising:

about 5% of minoxidil;
about 53% of a polyol;
about 26% of an alcohol;
from about 0.25% to about 1% of an acrylate/C₁₀₋₃₀ alkyl acrylate crosspolymer.